

Image

#1651

Practitioner's Docket No. 56970 (70301)

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Wieland, et al. Confirmation: 6225  
Application No.: 10/049,968 Art Unit: 1651  
Filed: February 13, 2002 Examiner: Weber, Jon P.  
For: SUBSTANCES AND AGENTS FOR POSITIVELY INFLUENCING  
COLLAGEN

Mail Stop Fee Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

AMENDMENT TRANSMITTAL

1. Transmitted herewith is a Response to Restriction Requirement for this application.

STATUS

2. [ ] a small entity. A statement:  
[ ] is attached.  
[ ] was already filed.  
[X] other than a small entity.

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. 1.8(a))

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

- ☒ deposited with the United States Postal Service  
with sufficient postage as first class mail in an  
envelope addressed to Mail Stop Fee  
Amendment, Commissioner for Patents, P.O.  
Box 1450, Alexandria, VA 22313-1450.

Date: February 17, 2004

FACSIMILE

- ☐ transmitted by facsimile to the Patent and  
Trademark Office.

Signature

*Helen Murray Tarbi*  
Helen Murray Tarbi

3.

### EXTENSION OF TERM

**NOTE:** *"Extension of Time in Patent Cases (Supplement Amendments) — If a timely and complete response has been filed after a Non-Final Office Action, an extension of time is not required to permit filing and/or entry of an additional amendment after expiration of the shortened statutory period.*

*If a timely response has been filed after a Final Office Action, an extension of time is required to permit filing and/or entry of a Notice of Appeal or filing and/or entry of an additional amendment after expiration of the shortened statutory period unless the timely-filed response placed the application in condition for allowance. Of course, if a Notice of Appeal has been filed within the shortened statutory period, the period has ceased to run." Notice of December 10, 1985 (1061 O.G. 34-35).*

**NOTE:** *See 37 C.F.R. § 1.645 for extensions of time in interference proceedings, and 37 C.F.R. § 1.550(c) for extensions of time in reexamination proceedings.*

4. The proceedings herein are for a patent application and the provisions of 37 C.F.R. § 1.136 apply.

*(complete (a) or (b), as applicable)*

(a) ☐ Applicant petitions for an extension of time under 37 C.F.R. § 1.136 (fees: 37 C.F.R. § 1.17(a)(1)-(4)) for the total number of months checked below:

	Extension (months)	Fee for other than small entity	Fee for small entity
<input checked="" type="checkbox"/>	one month	\$ 110.00	\$ 55.00
<input type="checkbox"/>	two months	\$ 420.00	\$ 210.00
<input type="checkbox"/>	three months	\$ 950.00	\$ 475.00
<input type="checkbox"/>	four months	\$ 1,480.00	\$ 740.00

Fee: \$ 110.00

If an additional extension of time is required, please consider this a petition therefor.

*(check and complete the next item, if applicable)*

☐ An extension for \_\_\_\_\_ months has already been secured. The fee paid therefor of \$ \_\_\_\_\_ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$

**OR**

(b) ☐ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition for extension of time.

## FEE FOR CLAIMS

5. The fee for claims (37 C.F.R. § 1.16(b)-(d)) has been calculated as shown below:

[Col. 1]	[Col. 2]	[Col. 3] Small Entity			Other Than a Small Entity	
Claims Remaining After Amendment	Highest No. Previously Paid For	Present Extra	Rate	Additional Fee	Rate	Additional Fee
Total	Minus	=	x \$ 9 =	\$0.00	x \$ 18 =	\$0.00
Indep.	Minu	=	x \$43 =	\$0.00	x \$ 86 =	\$0.00
[ ] First Presentation of Multiple Dependent Claim			+\$145 =		+ \$290 =	
			Total Addit. Fee: \$		Total Addit. Fee \$	

- 
- \* If the entry in Col. 1 is less than the entry in Col. 2, write "O" in Col. 3,  
 \*\* If the "Highest No. Previously Paid For" IN THIS SPACE is less than 20, enter "20".  
 \*\*\* If the "Highest No. Previously Paid For" IN THIS SPACE is less than 3, enter "3".  
 The "Highest No. Previously Paid For" (Total or Indep.) is the highest number found in the appropriate box in Col. 1 of a prior amendment or the number of claims originally filed.

**WARNING:** "After final rejection or action (§ 1.113) amendments may be made canceling claims or complying with any requirement of form which has been made." 37 C.F.R. § 1.116(a) (emphasis added).

(complete (c) or (d), as applicable)

(c) ☒ No additional fee for claims is required.

**OR**

(d) ☐ Total additional fee for claims required \$

## FEE PAYMENT

6. ☐ Attached is a check in the sum of \$  
☐ Charge Account No. 04-1105 the sum of \$  
 A duplicate of this transmittal is attached.

## FEE DEFICIENCY

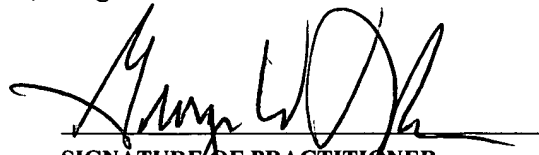
*NOTE: If there is a fee deficiency and there is no authorization to charge an account, additional fees are necessary to cover the additional time consumed in making up the original deficiency. If the maximum, six-month period has expired before the deficiency is noted and corrected, the application is held abandoned. In those instances where authorization to charge is included, processing delays are encountered in returning the papers to the PTO Finance Branch in order to apply these charges prior to action on the cases. Authorization to charge the deposit account for any fee deficiency should be checked. See the Notice of April 7, 1986, (1065 O.G. 31-33).*

7. ☒ If any additional extension and/or fee is required, charge Account No. 04-1105.

## AND/OR

- ☒ If any additional fee for claims is required, charge Account No. 04-1105.

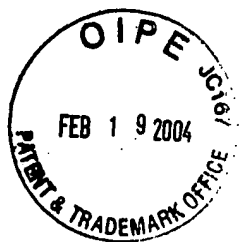
Tel. No.(617) 439-4444  
Date: February 17, 2004



SIGNATURE OF PRACTITIONER  
George W. Neuner (Reg. 26964)  
Edwards & Angell, LLP  
PO BOX 55874  
Boston, MA 02205

Customer No. 21,874

BOS2\_434047.1



Docket No. 56970 (70301)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application: Wieland, et al.

Examiner: Weber, Jon P.

Application No.: 10/049,968

Art Unit: 1651

Filed: February 13, 2002

Confirmation: 6225

For: SUBSTANCES AND AGENTS FOR POSITIVELY INFLUENCING COLLAGEN

\*\*\*\*\*

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service, Postage prepaid, in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 17, 2004.

By: Helen Murray Tarbi  
Helen Murray Tarbi

\*\*\*\*\*

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**RESPONSE TO RESTRICTION REQUIREMENT**

In the Office Action dated December 17, 2003, restriction is required to one of the following inventions:

- I. Claims 27-40, drawn to a method of restoring collagen by administering a substance which inhibits the production or effect of estrogens.
- II. Claim 41, drawn to a method of restoring collagen and of treating myocardial or brain infarctions.
- III. Claims 42, drawn to a method of restoring collagen and of treating osteoporosis.
- IV. Claim 43, drawn to a method of restoring collagen and of treating arteriosclerosis.

02/24/2004 MAHME1 00000002 10049968

01 FC:1251

110.00 OP

- V. Claim 44, drawn to a method of restoring collagen and of treating urinary incontinence.
- VI. Claim 45, drawn to a method of restoring collagen and of treating excessive production of glucocorticoids.
- VII. Claim 46, drawn to a method for treating decrease hair growth.
- VIII. Claim 47, drawn to a method for treating wrinkles, etc.
- IX. Claim 48, drawn to a method of treating effects of sun exposure to the skin.
- X. Claim 49, drawn to a composition comprising a first compound that inhibits the production or effects of estrogens and a second compound that inhibits the production or effects of dihydroxytestosterone.
- XI. Claim 50, drawn to a composition comprising an aromatase inhibitor and a 5- $\alpha$ -reductase inhibitor.
- XII. Claim 51, drawn to a composition comprising a compound that inhibits both of (1) the production or effects of estrogens, and (2) the production or effects of dihydroxytestosterone.
- XIII. Claim 52, drawn to a composition comprising a compound that inhibits both (1) aromatase and (2) 5- $\alpha$ -reductase.

Applicants hereby elect the invention of Group I, claims 27-40, with traverse, for further examination in the present application. Applicants reserve the right to pursue the inventions of Group II – Group XIII in a divisional application.

#### Argument

This application is in the national stage of a PCT application. Thus, unity of invention is the proper criteria for examination of claims in this application. The unity of invention of the subject matter in present claims 27-40, 41-45 and 47-48 has been decided under Rule 40.2(c) during examination in the international phase of the PCT application.

The enclosed Decision W0003/02 follows from the Applicants' protest in the present case under Rule 40.2 (c) of the preceding PCT-procedure. In the International Search Report and the IPER (see Continuation of Section IV), ten groups of inventions had been listed (see also page 4, third paragraph of the Decision). The Board of Appeal of the EPO, however, decided (see page 17, penultimate paragraph and the judgment on page 18) that the originally listed groups 1 to 5 relate to one single invention based on novel applications of aromatase inhibitors (i.e. species compounds 1 that relate to groups 1 to 5 listed in the Decision), whereas groups 6 to 10 relating to the applications of antiestrogens are regarded as five separate inventions.

Please note that the aromatase inhibitors in the present context can be referred to the particular technical features under Rules 13.1 and 13.2 PCT for the claimed "substance which inhibits the production of estrogens" (see application, page 8, line 19 to page 14, line 12), whereas anti-estrogens can be referred to the particular technical features for the claimed "substance which inhibits the effect of estrogens" (page 8, lines 15 to 19 and page 14, lines 14 to 23).

Accordingly, the Appeal Board of the EPO acknowledged that there is **a single inventive concept** at least for those groups of inventions which relate to a substance that inhibits the production of estrogens. Please note that the judgment of the EPO includes an assessment of unity of invention *a posteriori*, i.e., taking prior art such as the cited EP 776,661 into account (page 15, 5<sup>th</sup> paragraph of the Decision).

If a complete English translation of Decision W0003/02 is required, please let Applicants know.

Hence, the following groups of claims, that are listed in the present Office Action and using the Examiner's renumbering of claims 27-52, share a common inventive concept, i.e., have unity of invention, when the compounds inhibit estrogen production. Thus, Groups I-VI and VIII-IX; claims 27-40, 41-45, and 47-48 have unity of invention and, in accord with the PCT, must be examined together. The shared technical feature is: the application of compounds that inhibit estrogen production. The shared technical effect is: stabilization, increase and/or restoration of collagen.

For the explanation of the relation between the elected species of compounds (that inhibit estrogen production) and the effects thereof, reference is made to page 19, bottom paragraph and the sections relating to the various application fields such as skin, other collagen containing body regions, osteoporosis, glucocorticoid-associated conditions, myocardial infarction, brain infarction and arteriosclerosis, urinary incontinence and excessive production of vitamin D and “after sun” – application on pages 21 to 33.

From the above discussion, it follows that a single inventive concept is given for claims 27 to 45 and 47 to 48, wherein the substance inhibits estrogen production. Because of the established unity of invention, these claims should be examined together in the present application.

Therefore, for claims 27-45 and 47-48 for compounds inhibiting estrogen production, it is respectfully submitted that a single general inventive concept under PCT Rules 13.1 and 13.2 is present, in full agreement with the Decision W0003/02.

Applicants reserve the right to file divisional application(s) directed to the remaining group of claims, which also have been found to have unity of invention.

## II. Election of Species

Applicants also are required to elect one of the following species:

Species 1, compounds that inhibit estrogen production – relevant to Groups I-IX and XII.

Species 2, compounds that inhibit the effects of estrogens – relevant to Groups I-IX and XII.

Species 3, compounds that inhibits the production dihydroxytestosterone – relevant to Group I, claim 24, and Groups X and XII.



Applicants hereby elect the Species 1, compounds that inhibit estrogen production. Applicants reserve the right to pursue the inventions of Species 2 and 3 if necessary in a divisional application, if no generic claim is allowed.

A petition has also been filed herewith requesting a one (1) month extension of time to February 17, 2004 to respond to the above referenced Office Action.

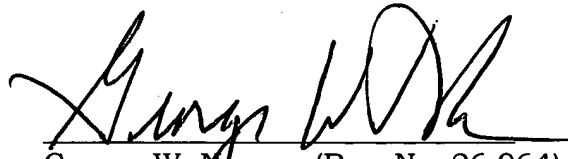
Applicants also conditionally petition for a further extension time to provide for the possibility that such a petition is required. As indicated below, please charge Deposit Account No. **04-1105** for the required fee.

An early examination and notice of allowance are earnestly solicited.

Respectfully submitted,

Date:

17 Feb. '04



George W. Neuner (Reg. No. 26,964)  
EDWARDS & ANGELL, LLP  
P.O. Box 55874  
Boston, MA 02205  
Tel: (617) 439-4444

Customer No. 21874